

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE BIOGEN '755 PATENT
LITIGATION**

**Civil Action No.: 10-2734 (CCC)(JBC)
(consolidated)**

OPINION

CECCHI, District Judge.

Before the Court are: (1) EMD Serono, Inc. and Pfizer Inc.'s ("Serono") Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103 (ECF No. 505); (2) Serono's Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 112 (ECF No. 501); (3) Bayer Healthcare Pharmaceuticals Inc.'s ("Bayer") Motion for Summary Judgment of Invalidity No. 1 – Obviousness-Type Double Patenting (ECF No. 503); (4) Bayer's Motion for Summary Judgment of Invalidity No. 2 – Anticipation by the Treatment References (ECF No. 506); (5) Bayer's Motion for Summary Judgment of Invalidity No. 3 – Lack of Written Description (ECF No. 509); (6) Bayer's Motion for Summary Judgment of Invalidity No. 4 – Anticipation by the Goeddel Patent (ECF No. 513); (7) Bayer's Motion for Summary Judgment No. 5 – Partial Summary Judgment Limiting Damages (ECF No. 517); and (8) Bayer's Motion for Summary Judgment No. 6 – Anticipation by the Weissmann Patent (ECF No. 624). Biogen MA, Inc. ("Biogen") opposes each motion. ECF Nos. 557, 558, 559, 560, 561, 562, 563, 633. The Court heard oral argument on August 10, 2017 and August 11, 2017. The Court has considered the parties' written submissions and oral presentations, including additional briefing subsequent to oral argument (ECF Nos. 656, 659). For the reasons discussed below, the Court denies each motion.

I. BACKGROUND

A. The Patent-In-Suit

In this patent infringement action, Biogen has asserted claims from U.S. Patent No. 7,588,755 (the “’755 patent” or “patent-in-suit”) against Bayer, Serono, and Novartis Pharmaceuticals Corp. (“Novartis”). The ’755 patent claims a method for immunomodulation, or treating viral diseases, cancers, or tumors, by administering to a patient a recombinant polypeptide—human interferon beta (“interferon- β ” or “HuIFN- β ”)—that is produced by a non-human host transformed by a recombinant DNA molecule.

Claim 1 of the ’755 patent recites:

1. A method for immunomodulation or treating a viral conditions [*sic*], a viral disease, cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

a recombinant polypeptide produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

- (a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C., and which code for a polypeptide displaying antiviral activity, and
- (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

As discussed in the Court’s claim construction Opinion, (ECF No. 403), the interferon relevant to this action is a “small, acid stable (glyco)-protein[] that render[s] cells resistant to viral infection.” (’755 patent at 1:39-40.) “Human interferon . . . has been classified into three groups

α , β and γ .” (*Id.* at 1:49-50.) Interferon- β is a protein natively produced by the human body. Bayer’s Reply to Biogen’s Response to Bayer’s Statement of Undisputed Material Facts (“SOF”) (Motion No. 2), ECF No. 598-1 ¶ 12.¹ Specifically, interferon- β is produced in “diploid fibroblast cells” and “in minor amounts . . . in lymphoblastoid cells.” (’755 patent at 1:50-53.) “[Hu]IFN- β is usually not detectable in normal or healthy cells.” (*Id.* at 2:40.) Instead, “the protein is produced as a result of the cell’s exposure to an IFN inducer.” (*Id.* at 2:41-42.) Such IFN-inducers “are usually viruses but may also be non-viral in character, such as natural or synthetic double-stranded RNA, intra-cellular microbes, microbial products and various chemical agents.” (*Id.* at 2:43-46.)

“Interferon therapy against viruses and tumors or cancers has been conducted,” (*id.* at 2:53-54), and “in addition to its use as an antiviral agent, HuIFN- β has potential application in antitumor and, anticancer therapy.” (*Id.* at 3:57-59.) “However, large-scale use of IFN as an antiviral agent requires larger amounts of IFN” than previously available. (*Id.* at 3:14-16.) Specifically, HuIFN- β “produced by human cell lines grown in tissue culture” resulted in a “low yield, expensive process.” (*Id.* at 4:49-50.) This problem was eventually solved by

locating and separating DNA sequences that code for the expression of HuIFN- β in an appropriate host thereby providing DNA sequences, recombinant DNA molecule and methods by which a host is transferred to produce a polypeptide displaying an immunological or biological activity of human fibroblast interferon.

(*Id.* at 6:48-53.) By virtue of this discovery, it was “possible to obtain polypeptides displaying an immunological or biological activity of HuIFN- β for use in antiviral, antitumor or anticancer

¹ Local Civil Rule 56.1 requires a party moving for summary judgment to file a statement of material facts not in dispute. An opposing party must file a responsive statement, addressing each material fact and “indicating agreement or disagreement and, if not agreed, stating each material fact in dispute and citing to the affidavits and other documents.” L. Civ. R. 56.1. Any material fact not disputed “shall be deemed undisputed” for purposes of deciding the motion. *Id.* All references to “SOF” throughout this Opinion refer to the parties’ Local Civil Rule 56.1 statements.

agents and methods.” (*Id.* at 6:54-59.)

Certain additional scientific concepts are relevant to the motions discussed below. The protein interferon- β is made up of building blocks called amino acids. DNA sequences are made up of nucleotides that each contains a base—adenine (“A”), cytosine (“C”), guanine (“G”), or thymine (“T”). Bayer’s Reply to Biogen Response to Bayer’s SOF (Motion No. 6), ECF No. 643-1 ¶ 14. A triplet of DNA nucleotides is known as a “codon,” which codes for a specific amino acid. *Id.* ¶ 15. Many amino acids have multiple corresponding codons. *Id.* ¶ 16. Different DNA sequences that code for the same protein are called “degenerate” sequences. *Id.*

DNA is normally double-stranded, with each base of each nucleotide pairing with its complement on the other strand to form a double helix. ECF No. 633 at 7. The bonds connecting the bases can be reversibly broken, resulting in complementary single strands. *Id.* Those single strands can then reassociate to form a double-stranded structure in a process called “hybridization.” *Id.* When two single strands of DNA come into proximity they may hybridize if the strands are sufficiently complementary. Bayer’s Reply to Biogen’s Response to Bayer’s SOF (Motion No. 6), ECF No. 643-1 ¶ 17. A hybridization experiment, such as a “Southern blot” test, assesses whether two DNA sequences are sufficiently complementary to hybridize. In such an experiment, DNA sequences that hybridize under one set of testing conditions may not hybridize under different conditions. *Id.* ¶ 24.

B. Prosecution of the ’755 Patent

Dr. Walter Charles Fiers is the sole named inventor on ’755 patent. The ’755 patent issued on September 15, 2009 from U.S. Application No. 08/449,930 (the “’930 application”), filed on May 25, 1995. The ’755 patent claims priority to U.S. Application No. 06/250,609 (the “’609 application”), filed on April 3, 1981, and a patent application filed in Great Britain on June 6, 1980

(the “British Application”).² During prosecution of the ’609 application, on April 15, 1982, the U.S. Patent and Trademark Office (“PTO”) made a restriction requirement separating the pending claims into five groups, one of which included a claim directed to a method of treatment. Biogen’s Response to Bayer’s SOF (Motion No. 1), ECF No. 589 ¶ 10. The ’609 application was abandoned in 1994. *Id.* ¶ 14.

Between the PTO’s restriction requirement in April of 1982 and the filing of the ’930 application in May of 1995, Biogen filed two divisional applications that contained method-of-treatment claims. Specifically, on July 28, 1989, Biogen filed divisional application U.S. Application No. 07/289,503. The PTO initially proceeded to examine those claims, but ultimately issued a restriction requirement on February 4, 1994. Bayer’s Reply to Biogen’s Response to Bayer’s SOF (Motion No. 1), ECF No. 597-1 ¶¶ 41-42. On June 3, 1994, Biogen filed its second divisional application, U.S. Application No. 08/253,843. The PTO issued another restriction requirement on December 21, 1994. *Id.* ¶¶ 43-44. On March 12, 1998, the PTO suspended prosecution of the ’930 application “indefinitely” due to a potential interference, and the application remained suspended until January 15, 2003. *Id.* ¶¶ 36-37.

II. PROCEDURAL HISTORY

On May 27, 2010, Bayer filed suit against Biogen seeking a declaration that Bayer does not infringe the ’755 patent claims and that the ’755 patent claims are invalid. ECF No. 1. On May 28, 2010, Biogen initiated a separate proceeding by filing suit against Bayer, Serono, and Novartis. C.A. No. 10-2760, ECF No. 1. Biogen’s infringement claims against Bayer and Novartis are based on the sale of interferon- β products Betaseron® and Extavia® in the United

² As discussed below, the parties dispute whether the ’755 patent claims are entitled to a June 6, 1980 filing date.

States for the treatment of MS via immunomodulation.³ C.A. No. 10-2760, ECF No. 1 at ¶¶ 50-73, ECF No. 61 at ¶¶ 60-83. Biogen's infringement claims against Serono are based on the sale of interferon- β product Rebif® in the United States for the treatment of MS via immunomodulation. C.A. No. 10-2760, ECF No. 1 at ¶¶ 32-49, ECF No. 61 at ¶¶ 42-59. Bayer, Novartis, and Serono claim that the '755 patent claims are invalid, not infringed, and/or unenforceable. On October 1, 2010, the previous Magistrate Judge entered a Pretrial Scheduling Order consolidating Bayer's declaratory judgment action with Biogen's patent infringement suit. ECF No. 37.

On March 28, 2016, the Court construed claim 1 of the '755 patent as reciting a "one-step method of 'administering' to a patient in need the specified recombinant HuIFN- β ." ECF No. 403 at 17. The Court also determined that the "produced" and "transformed" limitations of claim 1 are "merely descriptive of the recombinant polypeptide to be administered" as opposed to separate steps that must be shown to prove infringement. *Id.* at 14-15. The Court further construed the term "produced in a non-human host transformed by a recombinant DNA molecule" in claim 1 to mean "expressed by a transformed cell line that is not a human cell line, wherein a recombinant DNA molecule was/is incorporated into a cell such that it remains stably and non-transiently present in the cell, but does not necessarily need to be incorporated into the chromosome of the cell, wherein the incorporation typically occurs once and does not occur when a cell reproduces through the natural process of cell division." *Id.* at 17-18.

On October 27, 2017, the Court granted Bayer's and Serono's motions for severance. ECF No. 743. With respect to Biogen's action against Serono, a jury trial is scheduled to begin on January 18, 2018. *Id.*

³ Novartis's product Extavia® is manufactured by Bayer and is essentially re-branded Betaseron®. ECF No. 433 at 3. Accordingly, all references to Betaseron® in this Opinion include Extavia®.

III. LEGAL STANDARD

Summary judgment is appropriate if the “depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials” demonstrate that there is no genuine issue as to any material fact, and, construing all facts and inferences in a light most favorable to the non-moving party, “the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a), (c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The party moving for summary judgment bears the burden of demonstrating the absence of a genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). A fact is “material” if a dispute about that fact “might affect the outcome of the suit under governing [substantive] law,” and a “genuine” issue exists as to that fact “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* at 248. The Court’s role is to determine whether there is a genuine issue for trial, not to weigh the evidence and decide the truth of the matter. *Id.* at 249.

“Because patents are presumed valid, ‘a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of facts underlying invalidity that no reasonable jury could find otherwise.’” *Trimed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1340 (Fed. Cir. 2010) (quoting *SRAM Corp. v. AD-II Eng’g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006)).

IV. DISCUSSION

A. Serono’s Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103

Serono contends that Biogen—through prior sworn testimony of the ’755 patent inventor Dr. Fiers—admitted that the ’755 patent claims would have been obvious to a person of ordinary

skill in the art (“POSA”)⁴ as of June 6, 1980, and accordingly those claims are invalid under 35 U.S.C. § 103.⁵ A patent claim is invalid if “the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103(a). Obviousness is a legal conclusion based on underlying factual determinations, including (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness. *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016).

In support of its obviousness argument, Serono relies on statements made in a sworn affidavit by Dr. Fiers, which Biogen submitted to the Canadian Patent Office on November 22, 2001 during a conflict proceeding involving Dr. Fiers’ Canadian Application No. 374,378 (the “Fiers Affidavit”).⁶ Serono’s SOF, ECF No. 505-6 ¶¶ 8-32; Appendix B, ECF No. 505-8. Serono argues that by submitting the Fiers Affidavit, “Biogen explicitly took the position that, once a [POSA] had the DNA sequence for IFN-β, everything else—producing the IFN-β polypeptide, and administering it to a patient for anti-viral and anti-tumor purposes—would have been ‘routine’ and ‘obvious.’” ECF No. 505-1 at 3. According to Serono, the statements in the Fiers Affidavit are party admissions of Biogen to which Biogen is bound and cannot in fairness contradict. ECF No.

⁴ In this Opinion, the Court will refer to a person of ordinary skill in the art as a “POSA.” This term includes all iterations of this concept, such as “a person having ordinary skill in the art,” “one of ordinary skill in the art,” etcetera.

⁵ For purposes of its motion, Serono uses a filing date of June 6, 1980. ECF No. 505-1 at 1 n.1.

⁶ In Canada, conflicts were declared “when two or more pending patent applications filed before October 1, 1989 . . . (a) each contained one or more claims defining substantially the same invention, or (b) when one or more claims of one application described the invention disclosed in the other application.” ECF No. 569 ¶ 14. The purpose of such proceedings is to “decide which of two or more applicants is the earlier inventor of, and thus gets priority for, subject matter that is claimed in a co-pending application(s).” *Id.*

647 at 6-11. Serono acknowledges that if the Court determines that Biogen is not bound by the statements in the Fiers Affidavit, then conflicting evidence warrants denial of its motion. 8/10 Tr., ECF No. 750 at 15:9-14.

To the extent that Serono relies on the Fiers Affidavit as an admission of the obviousness of the '755 patent claims, there are genuine issues of material fact regarding the content of the document and context in which it was submitted that are appropriate for a jury's consideration in the first instance and, hence, preclude summary judgment. Construing the facts in the light most favorable to Biogen, a reasonable jury could find, as Biogen asserts, that the sections of the Fiers Affidavit relied on by Serono at most concern protein expression and thus have little to no bearing on the validity of method of treatment claims. ECF No. 557 at 23-29. In addition, the record reveals a genuine disagreement as to the significance, if any, of the fact that the Fiers Affidavit was filed in a Canadian proceeding involving different patentability standards and non-method patent claims.⁷ A jury would need to consider the evidence and decide what, if any, conclusions to draw from the Fiers Affidavit. For this reason alone, summary judgment is inappropriate.

Even if this Court were to agree with Serono that Biogen, through the Fiers Affidavit, undisputedly admitted that methods of treatment using recombinant interferon- β are obvious, Serono has failed to establish by clear and convincing evidence that the statements in the Fiers Affidavit are legally dispositive of the obviousness of the '755 patent claims. The authorities upon which Serono relies do not provide that a district court may substitute an obviousness conclusion

⁷ Indeed, Serono's expert opined that the differences between the obviousness standards in Canada and the United States "could be the subject of a master's degree," (ECF No. 587 at 161:23-162:6), and that the standard for inventiveness in Canada has fluctuated over time and can carry different meaning depending on context (*id.* at 38:13-21, 161:2-162:15).

drawn by a party or inventor in a foreign proceeding in place of its own analysis.⁸

Serono primarily relies on *In re Cygnus Telecommunications Technology, LLC, Patent Litigation*, 536 F.3d 1343 (Fed. Cir. 2008), for the proposition that a party cannot create a genuine issue for trial simply by contradicting its prior sworn statements without explaining the contradiction or attempting to resolve the disparity. In *Cygnus*, the Federal Circuit affirmed the district court's grant of summary judgment of invalidity under 35 U.S.C. § 102(b)'s on-sale bar. During prosecution of the application that issued as the patent-in-suit, the inventor submitted a sworn declaration to the PTO claiming to have reduced his invention to practice as of a certain date. *Id.* at 1353. Later during litigation, the patentee submitted an affidavit by the inventor that contradicted statements from the inventor's earlier declaration regarding the reduction-to-practice date. The Federal Circuit agreed with the district court that the patentee was bound by the inventor's statements in the earlier declaration and had "simply failed to offer sufficient evidence before the district court to undermine the force of his sworn admission regarding the date that he reduced his invention to practice." *Id.* at 1354. Thus, *Cygnus* at most suggests that alleged admissions should be considered with genuine factual disputes.⁹ See also *Messerschmidt v. United States*, 29 Fed. Cl. 1, 31, 33, 39 (Ct. Fed. Cl. 1993) (citing plaintiff-inventor's deposition testimony among other record evidence showing the claimed invention was obvious over certain prior-art references in the context of addressing factual inquiries of the obviousness analysis).

⁸ The obviousness inquiry is undertaken from the perspective of a POSA. The Federal Circuit prohibits conducting an obviousness inquiry from the inventor's point of view. See *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997) ("The decision of obviousness *vel non* is made not from the viewpoint of the inventor, but from the viewpoint of a person of ordinary skill in the field of the invention.").

⁹ The date of reduction to practice to which the admission in *Cygnus* related is an underlying factual determination in the on-sale bar analysis under U.S. law. See *id.* at 1353. By contrast, the alleged admissions here concern an ultimate legal conclusion in a foreign patent proceeding.

Serono also cites cases in this district and the Federal Circuit for the proposition that a party is bound by and cannot later contradict admissions previously made in a foreign patent tribunal.¹⁰ None of these cases address the particular issue raised here—namely, whether an inventor’s sworn statements made in a foreign patent proceeding involving a separate, foreign patent application are binding on a party in the context of an obviousness determination in litigation in the United States. At most, these cases suggest that the Court may consider statements made to foreign patent offices as relevant evidence in its overall analysis. Thus, Serono’s cited cases do not support its position that summary judgment of obviousness may be granted on the sole basis that Biogen is bound by previous sworn testimony made in a separate proceeding abroad. For this additional reason, summary judgment is inappropriate.

Accordingly, the Court denies Serono’s motion for summary judgment of invalidity under 35 U.S.C. § 103.

B. Serono’s Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 112

Serono contends that the ’755 patent claims are invalid for lack of enablement and written description under 35 U.S.C. § 112.

i. Framework

A key dispute between the parties with respect to Serono’s motion is whether a patent claiming a method of treatment using recombinant polypeptides that are made in non-human host cells must enable and describe the full scope of non-human hosts and protein expression using those hosts. Biogen contends that Serono mischaracterizes the ’755 patent claims, which cover

¹⁰ *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367 (Fed. Cir. 2005); *Tanabe Seiyaku Co. v. U.S. Int’l Trade Comm’n*, 109 F.3d 726 (Fed. Cir. 1997); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, No. 04-754, 2006 WL 3041102 (D.N.J. Oct. 26, 2006); *Gallant v. Telebrands Corp.*, 35 F. Supp. 2d 378 (D.N.J. 1998).

methods of treating patients using recombinant polypeptides, not the transformed non-human hosts themselves or methods of expression using those hosts. ECF No. 558 at 20. Biogen relies on this Court's construction of the claim language "produced by a non-human host" as "not [a] method step" but instead "merely descriptive of the recombinant polypeptide to be administered." In other words, making the polypeptide is not a claim element.

Serono relies on *University of Rochester v. GD Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004) for the proposition that characterizing a claim as a method of using a compound as opposed to a claim to the compound itself is a "semantic distinction without a difference." ECF No. 596 at 4. Serono cites the *Rochester* court's statement that "[r]egardless whether a compound is claimed *per se* or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound." 358 F.3d at 926. The claims at issue were directed to methods "for selectively inhibiting PGHS-2 activity in a human host" by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product." *Id.* at 918. In other words, the patent claimed a genus of compounds by their function (i.e., ability to selectively inhibit the activity of PGHS-2).¹¹ The patent's specification did not, however, describe any specific compound capable of performing the claimed method of selectively inhibiting PGHS-2 or any method for making such compound. Moreover, the patentee did not present any evidence that a POSA would have been able to identify any such compound

¹¹ Similarly, in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc), the Federal Circuit characterized claims directed to methods of reducing NF- κ B binding as "genus claims, encompassing the use of all substances that achieve the desired result of reducing the binding of NF- κ B to NF- κ B recognition sites." *Id.* at 1341. The court reasoned that to satisfy the written description requirement, "the specification must demonstrate that [the patentee] possessed the claimed methods by sufficiently disclosing molecules capable of reducing NF- κ B activity." *Id.* at 1355. Of note, the written description issue was decided by the jury in the first instance. *See id.* at 1355-58.

based on the specification's "vague functional description," and it was "undisputed that there was no pre-existing awareness in the art of any compound having [PGHS-2] selective activity." *Id.* at 928, 930.

This Court finds instructive the discussion of *Rochester* in *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, No. 15-1202, 2016 WL 6138124 (E.D. Tex. Oct. 21, 2016). The claims at issue in *UroPep* were directed to a method of treating benign prostatic hyperplasia ("BPH") by administering "an effective amount of an inhibitor of phosphodiesterase (PDE) V." *Id.* at *2. The defendants argued on summary judgment that the claims lacked written description support because the specification did not disclose the full scope of possible inhibitors. *Id.* at *15. The court observed that the claims were directed to the use of inhibitors to treat a condition, not to the discovery of the inhibitors themselves. *Id.* The court concluded that since "at least some PDE V inhibitors were known and were disclosed in the [patent] specification, the written description issue [did] not turn on whether the patentees were in possession of the entire genus of PDE V inhibitors."¹² *Id.* In addressing *Rochester*, the *UroPep* court explained that:

[I]t made sense for the [*Rochester*] court to say that the written description requirement was the same whether the claims were directed to inhibitors of PGHS-2 activity or to methods of inhibiting PGSH-2 activity, as the essence of the invention was the same in both cases—the identification of compounds that would inhibit PGHS-2 activity.

In this case, by contrast, the invention is not a method for inhibiting PDE V, which would be analogous to the invention in the *Rochester* case. Instead, the invention is a method of treating BPH by using inhibitors of PDE V. Because the invention is not the identification

¹² Similarly, in *Regents of University of California v. Dako North America, Inc.*, No. 05-3955, 2009 WL 1083446 (N.D. Cal. Apr. 22, 2009), the patent-in-suit claimed a method of staining chromosomal DNA through the use of probes. The district court denied defendant's motion for summary judgment for lack of written description. The court noted that "it is not the number of probe species used in the generic method that must be described in representative number in order to meet the written description requirement." *Id.* at *9.

of particular inhibitors, but the use of compounds having the inhibiting feature for a particular therapeutic purpose, the particular risk presented in *Rochester*—that the inventor is seeking claim coverage for a genus of compounds that perform a particular function, while only disclosing a small and unrepresentative subset of such compounds—is not directly presented here.

UroPep, 2016 WL 6138124, at *16. Similarly, here, the '755 patent claims are directed to the use of recombinant polypeptides having a certain feature (i.e., they were made using a non-human host) for a particular therapeutic purpose. As Biogen points out, the invention is not “new expression systems to recombinantly express IFN- β ” or “new hosts to use to recombinantly express IFN- β .” ECF No. 558 at 23-24. Thus, as in *UroPep*, the “danger of preempting fundamental technology” does not appear to apply to the method-of-treatment claims at issue. *Id.* at 23. Accordingly, the Court finds that it is not the genus of expression systems that must be enabled and described, it is the method of treatment that must be enabled and described.¹³ Moreover, as discussed below, Serono’s motion raises genuine factual disputes under either the *Rochester* or *UroPep* framework, thereby precluding summary judgment.

ii. Enablement

The first paragraph of 35 U.S.C. § 112 requires, *inter alia*, that the specification of a patent enable any person skilled in the art to which it pertains to make and use the full scope of the claimed invention. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1337 (Fed. Cir. 2005). To invalidate a patent for lack of enablement, “a challenger must show by clear and

¹³ The *UroPep* court suggested that its distinction of *Rochester* “might not have much force” if the patent-in-suit’s specification “had disclosed very little information about PDE V inhibitors, or had provided no examples of such inhibitors.” 2016 WL 6138124, at *16. Serono correctly observes that in *UroPep*, “there were hundreds of known PDE V inhibitors” as of the priority date. *Id.* While the particular facts in *UroPep* may not be identical to those here, as discussed further below, in contrast to the patentee in *Rochester*, at this stage Biogen has identified sufficient evidence to send the written description issue to the jury.

convincing evidence that a [POSA] would not be able to practice the claimed invention without undue experimentation.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1309 (Fed. Cir. 2015) (citation and internal quotations omitted). “Enablement is determined as of the effective filing date of the patent’s application.” *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). Enablement is a question of law based on underlying factual inquiries. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (noting that the analysis of undue experimentation “is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations”). The factors that a court may consider in determining whether a disclosure would require undue experimentation are: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *Id.*

Serono argues that the ’755 patent specification fails as a matter of law to enable claims to recombinant polypeptide expression in the full range of “non-human host” cells.¹⁴ Specifically, Serono asserts that while the patent broadly claims the use of recombinant interferon- β polypeptides made in “the millions of species on Earth other than humans,” the specification discloses production of such polypeptides in only two species of non-human hosts—*Escherichia Coli* (“*E. coli*”) bacteria and monkey cells. ECF No. 502 at 2, 6. Serono relies on alleged admissions by Dr. Fiers and Biogen’s experts that as of June 1980, bacterial hosts such as *E. coli* were the only hosts available for the expression of cloned DNA sequences, and that as of April 1981, Dr. Fiers had only worked in *E. coli* and monkey cells. *Id.* at 20-21.

¹⁴ Serono uses April 3, 1981 as the priority date of the ’755 patent claims for purposes of its motion. ECF No. 502 at 6 n.1.

Serono also cites Federal Circuit decisions assessing enablement of “claims drawn to recombinant production of polypeptides in broad groups of host cells.” *Id.* at 3. Serono contends that under this “controlling Federal Circuit precedent,” where the claimed host groups at issue were narrower in scope than the “non-human host” genus of the ’755 patent claims, and where the priority dates were later than April 1981, it was determined that practicing recombinant techniques in one or a few types of host cells did not enable claims to broad ranges of host cells.¹⁵ *Id.* at 4-5, 13-15. Thus, according to Serono, no reasonable jury could conclude that the ’755 patent’s disclosure would have taught POSAs as of April 1981 how to make recombinant interferon- β polypeptides in all “non-human hosts” without undue experimentation. *Id.* at 12.

As an initial matter, the Court is not persuaded that the ’755 patent claims “cannot be enabled as a matter of law” in light of prior Federal Circuit decisions. *Id.* The cited decisions, most of which address the issue of enablement outside the summary judgment context, merely reaffirm the fact-specific nature of this inquiry. *See Adang v. Fischhoff*, 286 F.3d 1346, 1355-58 (Fed. Cir. 2002) (affirming PTO’s rejection of claims to transformed tomato plant in light of record evidence and deficiencies in specification, which included a single working example of an “entirely different species” than the one claimed); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d

¹⁵ Serono cites *Plant Genetic Systems N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003) for the proposition that this Court may rely on prior factual findings in unrelated cases regarding the state of the art of recombinant DNA technology as a starting point for assessing enablement in this case. *See* ECF No. 502 at 4-5. In *Plant Genetic Systems*, following a bench trial the district court addressed the same factual question already addressed in a prior Federal Circuit decision *In re Goodman*, 11 F.3d 1046 (Fed. Cir. 1993)—i.e., the existence of reliable *Agrobacterium*-mediated transformation methods for use with monocots. 315 F.3d at 1342. The Federal Circuit determined that the district court’s reliance on *Goodman* as a starting point was proper where there was “no assertion that the district court exclude[d] evidence that could have rebutted the findings in *Goodman*.” *Id.* By contrast, it does not appear that the same factual questions here were addressed in the cases Serono relies on, and in any event, at this summary judgment stage, Biogen has sufficiently pointed to contrary evidence in the record.

1362, 1374-75 (Fed. Cir. 1999) (affirming district court's finding after bench trial that claims to antisense technology were not enabled after considering several *Wands* factors, including the fact that the specification provided "little guidance or direction as to the practice of antisense in cells other than *E. coli*"); *In re Goodman*, 11 F.3d 1046, 1050-52 (Fed. Cir. 1993) (affirming PTO's rejection of claims to a method for producing mammalian peptides in plant cells where the patentee did not adequately rebut the record evidence showing that practicing gene transformation in all plants would have required extensive experimentation); *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (affirming examiner's rejection of claims to all genetically-engineered cyanobacteria expressing a given protein where the patentee did "not effectively dispute[] the[] assertions" that the claimed genus was large, diverse, and poorly understood and that the patent's disclosure of one working example was insufficient under the circumstances).¹⁶ Therefore, this Court declines to find on summary judgment that the '755 patent claims are not enabled as a matter of law based on the cited authority. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1338 (Fed. Cir. 2003) (rejecting dissent's assertion that it is "black-letter law" that "disclosure of one or two species may not enable a broad genus"); *Chiron Corp. v. Abbott Labs.*, No. 93-4380, 1996 WL 209717, at *8 (N.D. Cal. Apr. 23, 1996) ("The rejection of claims to a broad category of host cells in one patent does not mean similarly broad claims, even to exactly the same host cells, in another patent are not enabled.").

¹⁶ Serono also relies on *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352 (Fed. Cir. 2007), in which the Federal Circuit affirmed the district court's grant of summary judgment of invalidity for lack of enablement. *Monsanto* is distinguishable. The claim at issue was to a chimeric plant gene that, like the claims in *Vaeck* and *Goodman*, was defined by "broad functional language"—i.e., the claimed gene had to "function in any plant cell, including both dicots and monocots." *Id.* at 1360-61. Based on the particular facts of that case, the court found lack of enablement because, *inter alia*, the "claim require[d] transformation of the plant cell" and the patent was filed "before transformation of monocot cells was possible." *Id.* at 1361.

Moreover, the Court disagrees with Serono that there is no factual dispute as to whether the '755 patent claims are fully enabled. The expert witnesses in this case have advanced detailed and plausible, but conflicting, opinions concerning the adequacy of the '755 patent's disclosure and what was known in the art as of April 1981. For example, the experts dispute the number of known non-human cell lines as of April 1981 that could be used to recombinantly express interferon- β . *See, e.g.*, Biogen's Response to Serono's SOF, ECF No. 580 ¶¶ 12, 22 (citing Green Decl. ¶¶ 114-21; Kaufman Decl. ¶¶ 19-40). The record also reveals disputes regarding what was known in the art in 1981 regarding recombinant polypeptide expression, the degree of predictability in the art in 1981, how much guidance is provided in the '755 patent specification, and what a POSA could have accomplished in 1981 without undue experimentation. *See* ECF No. 558 at 29-35. Such conflicting expert testimony raises genuine factual issues that are appropriate for consideration by a jury in the first instance and, hence, preclude summary judgment. *See, e.g.*, *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1384 (Fed. Cir. 2011) ("Where there is a material dispute as to the credibility and weight that should be afforded to conflicting expert reports, summary judgment is usually inappropriate."); *B-K Lighting, Inc. v. Fresno Valves & Castings, Inc.*, 375 F. App'x 28, 32 (Fed. Cir. Apr. 28, 2010) ("[C]onflict in expert declarations . . . created a genuine issue of material fact that made summary judgment inappropriate."); *Transonic Sys., Inc. v. Non-Invasive Med. Techs. Corp.*, 143 F. App'x 320, 329-30 (Fed. Cir. July 25, 2005) (finding "expert testimony sufficient to raise a genuine issue of material fact resisting summary judgment"); *Total Containment, Inc. v. Environ Prods.*, No. 99-1059, 1999 WL 717946, at *4 (Fed. Cir. Sept. 15, 1999) (recognizing that summary judgment is often inappropriate where a case depends on "specific, plausible and detailed testimony by dueling expert witnesses"); *Leader Techs., Inc. v. Facebook, Inc.*, No. 08-862, 2011 WL 1514701, at *2

(D. Del. Mar. 14, 2011) (denying summary judgment where experts “advanced detailed and plausible, but conflicting, opinions”).

Accordingly, the Court denies Serono’s motion for summary judgment of invalidity for lack of enablement under 35 U.S.C. § 112.

iii. Written Description

The written description requirement mandates that “the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). “[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Id.* Compliance with the written description requirement is a question of fact that must be assessed on a case-by-case basis. *Allergan*, 796 F.3d at 1308.

Serono contends that the ’755 patent claims lack written description support because Biogen (through its expert’s testimony) admitted that as of April 1981, Dr. Fiers possessed the claimed recombinant polypeptides in only *E. coli* and monkey cells.¹⁷ ECF No. 502 at 20-21. Serono also argues that even absent these admissions, in an unpredictable field such as

¹⁷ Factors for evaluating the disclosure’s adequacy with respect to genus claims include “the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.” *Ariad*, 598 F.3d at 1351. The Federal Circuit has held that “a sufficient description of the genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.” *Id.* at 1350 (citation omitted). “[A] patentee may rely on information that is ‘well-known in the art’ for purposes of meeting the written description requirement.” *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (citation omitted).

recombinant DNA, one or two working examples of “non-human hosts” fail as a matter of law to support a showing that the inventor possessed the full scope of the claimed hosts. *Id.* at 21-23. Thus, even under the clear and convincing evidence standard, Serono contends, a reasonable jury would be compelled to find that the ’755 patent specification provides an inadequate written description of the claimed invention.

By contrast, Biogen asserts that the proper question is whether a POSA would have perceived that Dr. Fiers possessed methods for determining biological activity and using interferon- β made in other host cells once Dr. Fiers showed that interferon- β made recombinantly in *E. coli* had biological activity akin to that of native interferon- β and provided assays to determine such activity. ECF No. 558 at 12-13; 8/10 Tr., ECF No. 750 at 88:6-12. According to Biogen, Serono provides no proof on this question. Biogen also argues that in addition to listing potential hosts, the specification teaches several factors that a POSA may consider when choosing the host, how to design the appropriate recombinant DNA molecule to transform the host, how to optimize expression in the transformed host, and how to assess whether the recombinantly expressed polypeptides have the necessary biological activity to be therapeutically useful. ECF No. 558 at 37-38. Biogen further contends that the predictability of the art of protein expression is a “hotly disputed factual issue” as revealed by conflicting expert testimony. *Id.* at 38.

The Court concludes that there are disputed issues of material fact as to whether the ’755 patent satisfies the written description requirement. Serono has not appeared to have cited a *per se* rule of no written description if only one or two examples is disclosed, and as discussed above with respect to enablement, there are factual disputes regarding the level of predictability in the art and how many non-human hosts for recombinant expression were known as of April 1981. While Serono highlights certain alleged omissions in the specification, “[w]hether the omissions from the

specification, viewed in light of the facts known to [POSAs] as of the priority date of the ['755] patent, render the specification insufficient to provide the necessary written description of the inventions of the ['755] patent is a factual issue” for the jury to decide. *UroPep*, 2016 WL 6138124, at *18. Overall, the Court finds that the instant motion presents a “battle of the experts” that is not amenable to resolution prior to the presentation of evidence. *See Crown Packaging*, 635 F.3d at 1384; *B-K Lighting*, 375 F. App’x at 32; *Transonic Sys.*, 143 F. App’x at 330; *Total Containment*, 1999 WL 717946, at *4; *Leader Techs.*, 2011 WL 1514701, at *2.

Accordingly, the Court denies Serono’s motion for summary judgment of invalidity for lack of written description support under 35 U.S.C. § 112.

C. Bayer’s Motion for Summary Judgment of Invalidity No. 1 (Obviousness-Type Double Patenting)

Bayer contends that claim 1 of the '755 patent is invalid for obviousness-type double patenting (“OTDP”) over claims 5 and 8 of U.S. Patent No. 6,127,332 (the “’332 patent” or “reference patent”). Invalidity for OTDP is a question of law based on underlying factual inquiries. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012). The doctrine applies to patents that have different expiration dates and are commonly owned or assigned. It involves an analysis of the claims of the earlier-expiring patent (or reference patent) and the later-expiring patent (including their differences) and whether the differences in subject matter between the claims render them patentably distinct. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001), *cert denied*, 534 U.S. 1109 (2002).

As part of this analysis, the Federal Circuit has set forth two tests to determine whether the claims are patentably distinct. Under the “one-way” test, the Court determines whether the asserted patent claim is patentably distinct from—i.e., obvious over or anticipated by—the reference patent claim. *See id.*; *see also In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998). Under

the “two-way” test, the Court determines whether the asserted patent claim is patentably distinct from the reference patent claim *and* the reference patent claim is patentably distinct from the asserted patent claim. See *In re Hubbell*, 709 F.3d 1140, 1149 (Fed. Cir. 2013) (citing *Berg*, 140 F.3d at 1432); *In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991). The two-way test arose out of a concern to “prevent rejections for [OTDP] when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in the reverse order of filing.” *Hubbell*, 709 F.3d at 1149 (quoting *Berg*, 140 F.3d at 1432). Whether the one-way or two-way test applies is a question of law, but the determination can be based on underlying factual findings. See *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997); *Janssen Biotech, Inc. v. Celltrion Healthcare Co.*, 211 F. Supp. 3d 364, 373 (D. Mass. 2016).

i. Differences Between the '332 and '755 Patent Claims

The '332 patent issued on October 3, 2000, approximately nine years before the '755 patent issued. ECF No. 504, Ex. 2. The '332 patent issued from U.S. Application No. 08/912,768, filed on August 18, 1997, a continuation of U.S. Application No. 08/475,774, filed on June 7, 1995, which in turn was a continuation of U.S. Application No. 08/213,448, filed on March 15, 1994. *Id.* The '332 patent expired in 2014. Biogen’s Response to Bayer’s SOF (Motion No. 1), ECF No. 589 ¶ 3. The '755 and '332 patents are commonly assigned to Biogen, (*id.* ¶ 1), but the patents do not share any named inventors, (*id.* ¶¶ 17, 19).

As discussed above, the Court has already construed claim 1 of the '755 patent. ECF No. 403. The parties appear to agree that in general terms, claims 5 and 8 of the '332 patent claim methods of treatment using specific interferon- β muteins having antiviral properties. ECF No. 504-22 at 9-10; ECF No. 559 at 2, 8. Claim 5 of the '332 patent recites:

5. A method for treating a disease selected from the group [sic] consisting of osteosarcoma, cervical dysplasia, leukemia, multiple myeloma, basal cell carcinoma, lymphoid malignancies, breast carcinoma, glioma, melanoma, papilloma virus, hepatitis, viral encephalitis, cytomegalovirus, herpes infections, and multiple sclerosis, in a patient comprising administration of an effective amount of an IFN- β mutein, wherein the IFN- β mutein has phe (F), tyr (Y), trp (W) or his (H) substituted for the val (V) at position 101 in wild type IFN- β , numbered in accordance with wild type IFN- β , and wherein the administration results in a therapeutic benefit.

Claim 8 of the '332 patent recites:

8. The method according to claims 5 or 6, wherein the mutein comprises the amino acid sequence:

The parties dispute the nature of the relationship between the '332 patent claims and claim 1 of the '755 patent, and cite expert testimony in support of their positions. *See* Biogen's Response to Bayer's SOF (Motion No. 1), ECF No. 589 ¶¶ 4-9. Specifically, Bayer contends that claims 5 and 8 of the '332 patent recite species of the broader genus of claim 1 of the '755 patent. ECF No. 504-22 at 8-10. By contrast, Biogen contends that the claims are more accurately described as overlapping genera. ECF No. 559 at 9-13. As discussed below, however, the crux of Bayer's motion is whether the one-way or two-way test applies, a question that, in the Court's view, rests on disputed factual issues.

ii. Application of the One-Way vs. Two-Way Test

One of the disputed issues in this case is whether the one-way or two-way test should be applied. Bayer contends that the two-way test does not apply because the undisputed facts show that, between April 1982 and May 1995, Biogen was partially responsible for the timing of the '755 patent's issuance. *See Hubbell*, 709 F.3d at 1149 ("[T]he two-way test is appropriate only in the 'unusual circumstance' where 'the PTO is solely responsible for the delay in causing the second-filed application to issue prior to the first.'" (quoting *Berg*, 140 F.3d at 1437)). Specifically, according to Bayer, Biogen could have filed a divisional or continuation application

claiming methods of treatment at any time after the PTO's April 15, 1982 restriction requirement and during the pendency of the '609 application, including during the pendency of Interference No. 101,096.¹⁸ 8/11 Tr., ECF No. 751 at 105:2-8. Bayer also contends that even if the analysis were solely focused on Biogen's prosecution activity during the "co-pendency period," which Bayer and Biogen appear to agree is from March 1994 to October 2000, (*see id.* at 108:3-19, 128:19-129:1), the undisputed record shows that Biogen was at least partially responsible for the delay. Bayer points to, *inter alia*, Biogen's (i) withdrawal of the treatment claims after the 1982 restriction requirement that rendered those claims unexamined (though still pending) by the PTO under 37 C.F.R. § 1.142(b) (*id.* at 150:6-21); (ii) decision not to begin prosecuting the treatment claims until filing the '930 application in May 1995; and (iii) filing of a defective terminal disclaimer on October 14, 1997, which resulted in a four-month delay of prosecution (*id.* at 108:20-109:6).

By contrast, Biogen asserts that it repeatedly prosecuted its treatment claims before and during the co-pendency period. Specifically, on July 20, 1984, Biogen attempted to add treatment claims to interference proceedings, and on July 28, 1989 and June 3, 1994, Biogen attempted to include treatment claims in divisional applications. *See* Biogen's Response to Bayer's SOF (Motion No. 1), ECF No. 589 ¶¶ 11, 38-44. On March 12, 1998, the PTO determined that the treatment claims were allowable but suspended prosecution for another interference, which lasted until January 15, 2003. *Id.* ¶¶ 36-37. The '332 patent issued during this five-year suspension. Thus, according to Biogen, but for the suspension, the '755 patent would have issued before the '332 patent issued. Biogen also characterizes the '332 patent as a later-filed "improvement" patent

¹⁸ Bayer concedes that summary judgment would be inappropriate if the Court were to conclude that the two-way test applies. 8/11 Tr., ECF No. 751 at 118:9-10.

and the '755 patent as the earlier-filed "foundational" patent, to which the two-way test is meant to apply. ECF No. 559 at 1-4, 15-16; *see also Braat*, 937 F.2d at 593 (stating that "applications for basic and improvement patents should not be penalized by the rate of progress of the applications through the PTO, a matter over which the applicant does not have complete control").

The Court finds that there are disputed factual issues that preclude granting Bayer's motion, regardless of whether the focus is solely on the co-pendency period. *See Engineered Prods. Co. v. Donaldson Co., Inc.*, 225 F. Supp. 2d 1069, 1111 (N.D. Iowa 2002), *vacated in part on other grounds*, 147 F. App'x 979 (Fed. Cir. 2005) (examining applicant's prosecution activity before and during the co-pendency period). Each side has presented timelines of the relevant events in prosecution in support of their arguments concerning whether Biogen had any responsibility for the '332 patent issuing before the '755 patent. The parties offer different interpretations of various events in their respective timelines. Considering the facts in the light most favorable to Biogen, a reasonable jury could find, as Biogen asserts, that Biogen did not take any steps to delay prosecution of the claims of the '755 patent and that the re-filing of the terminal disclaimer did not affect the timing of the issuance of the '755 and '332 patents. ECF No. 559 at 22. Alternatively, a reasonable jury could find, as Bayer asserts, that in response to the PTO's February 4, 1994 restriction requirement, and during the co-pendency period, Biogen could have elected to prosecute its treatment claims in the '503 divisional application. Instead, "Biogen elected to prosecute claims [in the '503 divisional application] other than those to methods of treatment." ECF No. 559 at 26. Similarly, in response to the PTO's December 21, 1994 restriction requirement for the '843 divisional application, and while the parent application to the '332 patent was pending, Biogen could have elected to prosecute its treatment claims in the '843 divisional application. It again chose to prosecute other claims and withdraw its treatment claims from consideration.

Hence, the record contains sufficient evidence from which a reasonable jury could find for either Biogen or Bayer on the issue of whether the PTO was solely responsible for the delay in prosecution of the '755 patent.

Even were the Court to agree with Bayer that the one-way test applies, it would still conclude that summary judgment is inappropriate. As an initial matter, Biogen notes that Bayer's experts have offered no opinions as to whether claim 1 of the '755 patent is patentably distinct over the '332 patent claims. ECF No. 559 at 30-33. At this stage, this Court cannot conclude that Bayer has "submit[ted] such clear and convincing evidence of facts underlying invalidity [for OTDP] that no reasonable jury could find otherwise." *Trimed*, 608 F.3d at 1340. Moreover, there remain genuine factual disputes regarding whether claim 1 of the '755 patent is anticipated by the claims of the '332 patent. For instance, the parties' experts disagree as to what is required to meet the hybridization limitation of claim 1 of the '755 patent for anticipation purposes. ECF No. 559 at 32-33.

Accordingly, the Court denies Bayer's motion for summary judgment of invalidity based on OTDP over the '332 patent claims.

D. Bayer's Motion for Summary Judgment of Invalidity No. 2 (Anticipation by Treatment References)

Bayer contends that claim 1 of the '755 patent is anticipated under 35 U.S.C. § 102(a) by prior art references that disclose the treatment of viral conditions by administering to patients native interferon- β ("Treatment References").¹⁹ According to Bayer, native interferon- β and

¹⁹ These Treatment References include J. Desmyter et al., "Administration of Human Fibroblast Interferon in Chronic Hepatitis-B Infection," *Lancet*, 25(2): 545-47 (1976); Kingham et al., "Treatment of HBsAg-positive Chronic Active Hepatitis with Human Fibroblast Interferon," *Gut*, 19(2):91-94 (1978); J. Dolen et al., "Fibroblast Interferon Treatment of a Patient with Chronic Active Hepatitis," *Am. J. Med.*, 67:127-31 (1979); W. Carter and J. Horoszewicz, "Purified Human Fibroblast Interferon in vivo: Skin Reactions and Effect on Bone Marrow Precursor Cells," *Cancer*

recombinant interferon- β made in Chinese hamster ovary (“CHO”) cells are the same “polypeptide” under the parties’ agreed-upon definition of the claim term—i.e., they share the same “linear array of amino acids.” Based on this match in sequence, Bayer contends, native interferon- β and recombinant interferon- β are the same product, and because “a different source and process of obtaining the same product of the claims . . . cannot confer novelty as a matter of law,” summary judgment of anticipation is appropriate. ECF No. 511-17 at 12. Serono joined Bayer’s motion. ECF No. 529.

Biogen does not dispute that “[t]he sequential order of the amino acid residues for native IFN- β is the same as the sequential order of the amino acid residues for recombinant IFN- β .” Biogen’s Response to Bayer’s SOF (Motion No. 2), ECF No. 575 ¶ 8. Nor does Biogen dispute that the “therapeutic use of recombinant IFN- β produced by transformed CHO cells is within the scope of Claim 1 of the Fiers ’755 Patent.” *Id.* ¶ 9. Rather, Biogen contends that Bayer has failed to demonstrate that the product administered in claim 1—whether that product is a polypeptide derived from recombinant expression using a non-human host or a pharmaceutical composition containing such polypeptide—is the same as native interferon- β (or a composition thereof) as required for anticipation. ECF No. 563 at 20.

As an initial matter, it is undisputed that none of the Treatment References disclose methods of treating patients by administering recombinant interferon- β , let alone recombinant

Letters, 7:243-49 (1979); and Sundmacher et al., “Human Leukocyte and Fibroblast Interferon in a Combination Therapy of Dendritic Keratitis,” *Albrecht v. Graefes Arch. Klin. Exp. Ophthalm.*, 208:229-33 (1978). ECF No. 511-17 at 6-7. It is undisputed that prior to June 6, 1980, fibroblast interferon compositions that comprise native interferon- β were known and used clinically, and that clinical applications using fibroblast interferon compositions that comprise native interferon- β were known and published. Biogen’s Response to Bayer’s SOF (Motion No. 2), ECF No. 575 ¶ 6. Biogen contends that those clinical applications did not, however, use recombinant interferon- β compositions, which are “materially different” from native interferon- β compositions. *Id.*

interferon- β made in a non-human host cell. Bayer's Reply to Biogen's Response to Bayer's SOF (Motion No. 2), ECF No. 598-1 ¶ 15. In addition, the Court finds that at this stage Bayer is not entitled to a judgment as a matter of law based on its contention that their shared amino acid sequence renders native interferon- β and recombinant interferon- β the same for purposes of anticipation. The Court agrees with Biogen that Bayer reads the claim term "polypeptide" in isolation rather than in the context of the claim. Claim 1 requires that the polypeptide have "antiviral activity" and be administered in a "therapeutically effective amount," which expert testimony in the record indicates is not possible from its amino acid sequence (i.e., the primary structure) alone. ECF No. 563 at 3-5, 11, 21-24. Rather, for a polypeptide to display biological activity, it must be folded into its appropriate three-dimensional structure. *Id.* Moreover, Biogen has presented record evidence, including expert testimony and portions of the '755 patent specification, indicating that the terms "polypeptide" and "protein" are used interchangeably. *Id.* at 15-18, 23-24.

The parties also dispute whether cases addressing anticipation in the context of product-by-process claims, including *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009) and *Cubist Pharmaceuticals Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641 (D. Del. 2014), are relevant to the anticipation analysis of claim 1. The parties agree that claim 1 is not a product-by-process claim. 8/11 Tr., ECF No. 751 at 87:19-20, 87:22-23. Even applying the anticipation standards set forth in these cases, the Court finds that summary judgment is inappropriate. The parties dispute whether the anticipation analysis turns on recombinant interferon- β being structurally *and* functionally different from native interferon- β , or whether either difference alone is sufficient to impart novelty. The Court need not decide whether both structural and functional differences are required in order to decide Bayer's motion. Bayer concedes that "no summary

judgment should issue” if “structure alone is enough to distinguish.” *Id.* at 6:23-7:6; *see id.* at 15:4-8, 18:1-3. In addition, the Court disagrees with Bayer that the record is undisputed with respect to a lack of any functional difference. Considering the evidence in the light most favorable to Biogen, a reasonable jury could find that there are functional differences between native interferon- β and recombinant interferon- β ,²⁰ (*see* Biogen’s Response to Bayer’s SOF (Motion No. 2), ECF No. 575 ¶ 10; ECF No. 656 at 2-3; 8/11 Tr., ECF No. 751 at 53:13-18, 70:4-7, 86:10-19), or at least find that Bayer has failed to show by clear and convincing evidence that no functional differences exist.

Accordingly, the Court denies Bayer’s motion for summary judgment of invalidity based on anticipation by the Treatment References.

E. Bayer’s Motion for Summary Judgment of Invalidity No. 3 (Lack of Written Description)

Bayer contends that claim 1 of the ’755 patent is invalid for lack of written description under 35 U.S.C. § 112. Specifically, Bayer argues that claim 1 encompasses an “incalculable number” of polypeptides that Dr. Fiers did not possess as of the invention date. ECF No. 510-7 at 4-7. Bayer contends that there are more than 19⁶⁶ polypeptides encoded by DNA that meet the hybridization limitation of claim 1, it was unpredictable as of the invention date which of those polypeptides would display antiviral activity, and that while the ’755 patent discloses interferon- β , it does not specifically disclose any interferon- β muteins. *Id.* at 6-10. Therefore, according to Bayer, under *Ariad*, claim 1 lacks written description because (1) one polypeptide (interferon- β)

²⁰ For instance, Biogen has pointed to record evidence of functional differences with respect to hydrophobicity and immunogenicity—i.e., propensity to cause an adverse immune-system response in patients. ECF No. 656 at 2. The parties dispute whether the ability to be mass produced is a functional difference. Since Biogen has pointed to evidence of functional differences other than manufacturing, the Court need not decide at this stage whether mass production constitutes a functional difference.

is not representative of a large, densely populated genus of polypeptides; and (2) as of the invention date there was no known correlation between the structure and activity of interferon- β muteins (i.e., no structural features common to the members of the genus of polypeptides). Serono joined Bayer's motion. ECF No. 530.

As discussed above with respect to Serono's motion for summary judgment of invalidity for lack of written description, it is the method of treatment, not the genus of expression systems, which needs to be described. Similarly, here, the Court concludes that it is not the recombinant polypeptides themselves that must meet the written description requirement. Even if the Court were to adopt Bayer's proposed framework in assessing whether the '755 patent satisfies § 112, it would still deny summary judgment. As an initial matter, none of Bayer's cited cases create a categorical rule that disclosure of a single species within a genus is, as a matter of law, insufficient to provide written description of a claim to the genus. Bayer relies on *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011) and *Wyeth & Cordis Corp. v. Abbott Laboratories*, No. 08-230, 2012 WL 175023 (D.N.J. Jan. 19, 2012), *aff'd*, 720 F.3d 1380 (Fed. Cir. 2013). The patents in *Boston Scientific* (and *Wyeth*) did not provide "any 'definitions, examples, or experimental methods . . . for determining whether a compound is a structurally similar analog as contemplated by the patentees.'" *Boston Sci.*, 647 F.3d at 1360 (citation omitted). The Federal Circuit agreed that there was "no guidance at all in the specification as to how to properly identify or choose the claimed analogs." *Id.* at 1365. Thus, on the particular facts of those cases, the patentees had failed to satisfy their factual burdens.

Moreover, disputed factual issues preclude granting summary judgment. The expert witnesses in this case have advanced detailed and plausible, but conflicting, opinions concerning the sufficiency of the '755 patent's disclosure. For instance, the parties and their experts dispute

whether the '755 patent discloses specific examples of interferon- β muteins or guideposts to identify muteins with antiviral activity. Biogen's Response to Bayer's SOF (Motion No. 3), ECF No. 576 ¶¶ 3, 4. The parties and their experts also dispute whether the '755 patent discloses a correlation between the structural features of interferon- β and its muteins and their functional biological activity. *Id.* ¶¶ 1, 2. Indeed, the parties and their experts dispute the scope of claim 1. Biogen and its experts contend that the claim "is relatively narrow and the criteria make clear that the claims only cover the use of recombinant IFN- β and recombinant polypeptides that are closely related to IFN- β " and, contrary to Bayer's assertion, "does not cover the use of over 19⁶⁶ polypeptides" or the "use of 'any of those trillions or more polypeptides' that 'also happen to have antiviral activity.'" *Id.* Overall, the Court finds that the instant motion presents another "battle of the experts" that is not amenable to resolution prior to the presentation of evidence, including testimony, and that a reasonable jury could agree with either side on these material disputed factual issues. *See Crown Packaging*, 635 F.3d at 1384; *B-K Lighting*, 375 F. App'x at 32; *Transonic Sys.*, 143 F. App'x at 330; *Total Containment*, 1999 WL 717946, at *4; *Leader Techs.*, 2011 WL 1514701, at *2.

Accordingly, the Court denies Bayer's motion for summary judgment of invalidity for lack of written description.

F. Bayer's Motion for Summary Judgment of Invalidity No. 4 (Anticipation by the Goeddel Patent)

Bayer contends that claim 1 of the '755 patent is anticipated by U.S. Patent No. 5,460,811 (the "Goeddel patent"), which Bayer asserts is prior art under 35 U.S.C. § 102(e)(2). Serono joined Bayer's motion. ECF No. 531. Section 102 provides, in relevant part, that "[a] person shall be entitled to a patent unless (e) the invention was described in . . . (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant

for patent.” 35 U.S.C. § 102(e)(2). Anticipation is a question of fact. *Purdue Pharma*, 811 F.3d at 1351.

The Goeddel patent issued on October 24, 1995 from a U.S. patent application that claims priority to U.S. Application No. 190,799 (the “’799 application”), filed on September 25, 1980. ECF No. 514, Ex. 1. Based on a review of the parties’ briefs and oral argument, resolving the anticipation question here entails deciding: (1) whether the Goeddel patent is entitled to a September 25, 1980 filing date; (2) whether claim 1 of the ’755 patent is entitled to a June 6, 1980 filing date; and (3) whether the Goeddel patent discloses each and every element of claim 1 of the ’755 patent.²¹

i. Whether the Goeddel patent is entitled to a September 25, 1980 filing date

The parties dispute whether the ’799 application—the earliest U.S. patent application that led to the Goeddel patent—contains adequate § 112 support for the Goeddel patent claims, such that the Goeddel patent can rely on the ’799 application’s September 25, 1980 filing date. The Goeddel patent can only be § 102(e) prior art to the ’755 patent if it is entitled to a September 25, 1980 filing date. As discussed above, compliance with the written description requirement is a

²¹ In opposition to Bayer’s motion, Biogen also contends that the Goeddel patent is not § 102(e) prior art because the Patent Trial and Appeal Board (“PTAB”) cancelled the Goeddel patent in 2012 during an interference proceeding. Thus, according to Biogen, the patent is not a “granted” patent under § 102(e) as its claims no longer exist, and thus it cannot rely on the filing date of the ’799 application. ECF No. 561 at 10-13. In response, Bayer argues that a patent does not cease to be prior art when it is cancelled after it issued; it is merely rendered unenforceable. ECF No. 600 at 1-4. Bayer also cites cases rejecting arguments that a patent found invalid or having expired precludes its use as an invalidating reference. *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1317 n.5 (Fed. Cir. 2006) (“Although we have previously held the ’723 patent invalid, it can still, of course, anticipate a later product patent.”) (citation omitted); *De Cew v. Union Bag & Paper Corp.*, 57 F. Supp. 388, 394 (D.N.J. 1944) (“The nonpayment of the taxes and the consequent lapse of the patent does not affect the relevancy of its pertinent disclosure.”). Given that Bayer’s motion raises disputed factual issues that preclude granting summary judgment, the Court need not address Biogen’s additional argument.

question of fact, and enablement is a question of law based on underlying facts. *Allergan*, 796 F.3d at 1308-09. Bayer contends that since Biogen did not present evidence rebutting Bayer's expert's testimony on this issue, summary judgment is appropriate. ECF No. 514-15 at 6; ECF No. 600 at 4-6.

The record demonstrates genuine disputes regarding whether the Goeddel patent is entitled to a September 25, 1980 filing date. A reasonable jury could conclude, as Biogen asserts, that the Goeddel patent claims are not adequately supported by the '799 application but rather rest in part on "new matter" added in later applications that led up to the Goeddel patent's issuance. ECF No. 561 at 13-18. Indeed, Bayer concedes that one of those later-filed applications is a continuation-in-part, which caused the Goeddel patent's disclosure to differ in places from that of the '799 application. ECF No. 514-15 at 5. The parties dispute whether those differences are relevant. *See id.*; ECF No. 561 at 16-18. For this reason alone, summary judgment is inappropriate.

ii. Whether claim 1 of the '755 patent is entitled to a June 6, 1980 filing date

The parties also dispute whether, pursuant to 35 U.S.C. § 119, the '755 patent is entitled to a filing date of June 6, 1980—the date the British Application was filed. If the '755 patent is entitled to a June 6, 1980 filing date, the Goeddel patent is not prior art and thus cannot anticipate. 8/10 Tr., ECF No. 750 at 119:1-2. Bayer argues that claim 1 of the '755 patent is only entitled to a filing date of April 3, 1981—the date the '609 application was filed—because the British Application does not sufficiently describe the subject matter of claim 1. Specifically, Bayer contends that the British Application is merely a "research plan" and discloses neither treatment by "immunomodulation" of conditions other than viruses, tumors, or cancers; treatment using "muteins"; nor making interferon- β in host cells other than bacteria. *Id.* at 125:16-21.

The record demonstrates genuine disputes regarding whether claim 1 of the '755 patent is entitled to a June 6, 1980 filing date. There is conflicting testimony about the sufficiency of the

British Application's disclosure. A reasonable jury could find, as Bayer and its experts contend, that references to "immunomodulation" are absent from the British Application and were only later added in the '609 application, evidencing that Dr. Fiers had not conceived of treatment by immunomodulation by June 6, 1980. ECF No. 514-15 at 13-16. Alternatively, a reasonable jury could find, as Biogen and its experts assert, that the British Application "is replete with examples and references to the immunomodulatory properties of IFN" and a POSA "would understand this as disclosing the use of IFN to affect the immune system regardless of [] whether the term 'immunomodulation' was used." ECF No. 561 at 26. A reasonable jury could also find that the British Application would have informed a POSA that "some IFN- β muteins would be close enough in structure to native, human IFN- β to retain biological activity" and "how to test whether any specific mutein has such activity." *Id.* at 30-31. Hence, the record contains sufficient evidence from which a reasonable jury could find for either Biogen or Bayer on the issue of whether the British Application provides an adequate disclosure to support claim 1 of the '755 patent. As with other motions addressed in this Opinion, the instant motion presents a "battle of the experts" that is not amenable to resolution prior to the presentation of evidence, including testimony. *See Crown Packaging*, 635 F.3d at 1384; *B-K Lighting*, 375 F. App'x at 32; *Transonic Sys.*, 143 F. App'x at 330; *Total Containment*, 1999 WL 717946, at *4; *Leader Techs.*, 2011 WL 1514701, at *2. For this additional reason, summary judgment is inappropriate.

iii. Whether the Goeddel patent discloses each and every limitation of claim 1

The final issue raised by Bayer's motion is whether the Goeddel patent discloses "each and every limitation of the claimed invention." *Purdue Pharma*, 811 F.3d at 1351. Biogen contends that Bayer has not presented any experimental evidence that the DNA sequence disclosed in the Goeddel patent would hybridize to one of the four DNA sequences recited in claim 1 of the '755 patent. ECF No. 561 at 39. According to Biogen, based on Bayer's own expert's testimony, such

testing is required. *Id.* By contrast, Bayer contends that the Goeddel patent's DNA molecule meets claim 1's hybridization limitation because it is degenerate to—i.e., encodes the same polypeptide (interferon- β) as—Serono's DNA molecule, which Biogen tested and accused of infringing claim 1. ECF No. 600 at 15. A reasonable jury, taking all the evidence in the light most favorable to Biogen, could find that Bayer has not proven, by clear and convincing evidence, that the Goeddel patent discloses each and every element of claim 1. This is a further reason to conclude that summary judgment is inappropriate.

Accordingly, the Court denies Bayer's motion for summary judgment of invalidity based on anticipation by the Goeddel patent.

G. Bayer's Motion for Summary Judgment No. 5 (Partial Summary Judgment Limiting Damages)

i. Whether Biogen's recovery from Bayer is limited to an equitable remuneration

Bayer contends that, pursuant to 35 U.S.C. § 154(c), any recovery by Biogen against Bayer for infringement is limited to "an equitable remuneration." Section 154(c) provides, in relevant part:

(1) Determination. The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) Remedies. The remedies of sections 283, 284, and 285 shall not apply to acts which—(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and (B) became infringing by reason of paragraph (1).

(3) Remuneration. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee

35 U.S.C. § 154(c).²² Bayer argues that the two conditions of § 154(c) are met: (1) “substantial investment was made” in the development of Bayer’s Betaseron[®]—approved by the FDA in 1993—prior to June 8, 1995; and (2) Biogen received the benefit of the 17-years-from-issuance term for the ’755 patent, which provided Biogen a later expiration date (September 15, 2026) than it would have had if instead the patent were to expire 20 years from filing (2001). ECF No. at 518-27 at 3. Thus, according to Bayer, Bayer’s allegedly infringing acts of selling Betaseron[®] between 2009 and the present “became infringing” by reason of § 154(c)(1). *Id.* at 11.

By contrast, Biogen contends that equitable remuneration does not apply in this case. Contending that Bayer is wrong on the law, Biogen asserts that for *issued* patents as of June 8, 1995 whose terms were retroactively extended beyond 17 years (so as to expire 20 years from the filing date), patentees may recover only an equitable remuneration for infringement during the time period between 17 years and expiry (i.e., the “Delta period”). ECF No. 562 at 1-2. Here, the ’755 patent issued *after* June 8, 1995. Moreover, according to Biogen, there is no Delta period because the ’755 patent received exactly the same 17-year-from-issuance term it would have received absent the URAA—i.e., the URAA did not extend the ’755 patent’s term beyond 17 years so as to create a Delta period. Thus, Bayer’s allegedly infringing acts did not “bec[o]me infringing by reason of” § 154(c)(1). *Id.* at 8-10. Biogen also contends that Bayer has adduced no evidence

²² The Uruguay Round Agreements Act (“URAA”) was signed into law on December 8, 1994. Pub. L. No. 103-465, 108 Stat. 4809 (1994). The URAA changed the term for a U.S. patent from 17 years from the patent’s issuance date to 20 years from the patent’s earliest effective filing date. 35 U.S.C. § 154(a)(2). For certain patents that were issued and for pending applications that were filed prior to June 8, 1995 (six months after enactment of the URAA), § 154(c)(1) preserves a guaranteed 17-year term, if it is longer than 20 years from filing. The ’930 application, which was filed on May 25, 1995 and issued as the ’755 patent, was pending before the PTO as of June 8, 1995. The ’755 patent expires on September 15, 2026—17 years from its issuance date of September 15, 2009.

of detrimental reliance on an expected shorter term. *Id.* at 12-14.

The Court finds that Bayer has not established that equitable remuneration under § 154(c) applies in this case. Bayer has not identified a case that has applied the equitable remuneration provision of § 154(c)(3) to a patent that issued from an application that was pending in the PTO on June 8, 1995. Although Bayer dismisses as dicta or minimally supported the discussions of equitable remuneration under § 154(c) in *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543 (Fed. Cir. 1996) and *TAP Pharmaceutical Products, Inc. v. Atrix Laboratories, Inc.*, No. 03-7822, 2005 WL 936926 (N.D. Ill. Apr. 22, 2005), this Court finds those cases instructive, particularly given the limited authority interpreting this statutory provision. These cases lend support to Biogen's interpretation of § 154(c)—namely, that the equitable remuneration provision only applies to patents that had issued by June 8, 1995 and limits available damages to infringing acts that occur during the Delta period (i.e., the part of the patent term beyond 17 years from issuance). Here, the '755 patent issued after June 8, 1995 and there is no Delta period, as the '755 patent has the same 17-year-term it had before the URAA. Thus, none of Bayer's alleged infringing acts "became infringing by reason of" § 154(c)(1). Accordingly, this Court finds that Bayer has not established that Biogen's award in this case is limited to equitable remuneration.

ii. Whether Biogen may recover lost profits

Bayer also contends that even if Biogen were entitled to pursue typical patent damages under 35 U.S.C. § 284, Biogen cannot recover lost profits because it did not sell any MS treatments to the U.S. market. Instead, non-party Biogen U.S. Corp. ("U.S. Corp."), a wholly-owned subsidiary of Biogen, sells the three MS drug products for which Biogen seeks lost profits—Avonex[®], Plegridy[®], and Tecfidera[®]. ECF No. 518-27 at 12-18. Bayer also contends that profits from U.S. Corp.'s sales of these products do not "inexorably flow" to Biogen. *Id.* at 18-24. See *Advanced Fiber Techs. (AFT) Trust v. J&L Fiber Servs., Inc.*, No. 07-1191, 2015 WL 1472015, at

*25 (N.D.N.Y. Mar. 31, 2015) (“‘Inexorable’ means that the profits flow automatically from the subsidiary to the parent; in other words, the subsidiary’s profits are the parent’s profits.”).

In opposition, Biogen contends that it may recover the profits it itself lost on intercompany, arm’s length sales to U.S. Corp. It is undisputed that Biogen and U.S. Corp., although related, function as separate companies. Biogen’s Response to Bayer’s SOF ¶ 8. Biogen explains that it sells the Avonex® drug substance (interferon-β) and the finished Plegridy® and Tecfidera® to U.S. Corp. in return for payment of an intercompany purchase price. 8/11 Tr., ECF No. 751 at 280:4-12. U.S. Corp. then sells those products to wholesalers and pharmacies. ECF No. 562 at 14. The lost profits that Biogen is principally seeking in this case are on the intercompany sales from Biogen to U.S. Corp. 8/11 Tr., ECF No. 751 at 279:13-15. Biogen also contends that it is entitled to recover profits of U.S. Corp.’s sales because those profits flow inexorably to Biogen.

On the present record, and upon review of the cited cases, the Court finds that the intrafamily, intercompany sales from Biogen to U.S. Corp. can constitute “sales” by Biogen for lost profits purposes. *See Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999) (“[T]rial courts, with this court’s approval, consistently permit patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the ‘but for world,’ and accordingly to recover lost profits in a wide variety of forms.”). Bayer has not appeared to have cited a blanket rule prohibiting the fact finder from considering such transactions in a lost profits analysis. In addition, construing the facts in the light most favorable to Biogen, the Court finds that Biogen has produced enough evidence that a rational juror could conclude that the profits of U.S. Corp. flow inexorably to Biogen. *See Advanced Fiber Techs.*, 2015 WL 1472015, at *25; *Corning Optical Commcn’s Wireless Ltd. v. SOLiD, Inc.*, No. 14-3750, 2015 WL 5723403, at *6-7 (N.D. Cal. Sept. 16, 2015). For these reasons, summary judgment is

inappropriate.

iii. Whether Rebif® should be taken into account as a non-infringing alternative

Bayer further argues that if Biogen is allowed to pursue lost profits, the hypothetical marketplace must include Serono's Rebif® as a non-infringing alternative. ECF No. 518-27 at 24-40. In response, Biogen contends that there is evidence in the record that Serono would not have exercised its option, which is a sufficient dispute of fact to deny summary judgment. ECF No. 562 at 33-34. For the reasons discussed in the Court's Opinion regarding Serono's motion for partial summary judgment as to Biogen's claim of lost profits, the Court finds there is a disputed issue of material fact as to whether Serono would have exercised its option, thus precluding granting Bayer's summary judgment motion. ECF No. 884.

Accordingly, the Court denies Bayer's motion for partial summary judgment limiting damages.

H. Bayer's Motion for Summary Judgment of Invalidity No. 6 (Anticipation by the Weissmann Patent)

Bayer contends that claim 1 of the '755 patent is anticipated by U.S. Patent No. 4,530,901 (the "Weissmann patent"), which Bayer asserts is § 102(e) prior art. The Weissmann patent discloses the recombinant production and use of human interferon alpha ("interferon- α "), along with the DNA sequence encoding interferon- α (designated "Hif-2h"). According to Bayer, the only dispute is whether the Weissmann patent meets the hybridization limitation of claim 1—i.e., whether it discloses a DNA molecule that is either (i) "capable of hybridizing" to one or more of the four interferon- β DNA inserts of claim 1; or (ii) "degenerate to" a DNA molecule that is so capable of hybridizing. ECF No. 627-1 at 4-5. Bayer contends that the Weissmann patent discloses the latter. Specifically, Bayer argues that Hif-2h is degenerate to a sequence—"Clone 4"—that, as confirmed through Bayer's expert's testing, is capable of hybridizing to two DNA

inserts (HFIF3 and HFIF6) recited in claim 1.²³ *Id.* at 14-18. According to Bayer, since the Weissmann patent meets the hybridization limitation, and since it is undisputed that the prior-art patent meets all the other limitations of claim 1, the Weissmann patent anticipates claim 1.

The parties previously agreed on the following construction of the hybridization limitation of claim 1:

capable of hybridizing to one or more of the nucleotide sequences inserted at the PstI restriction site of G-pBR322 selected from the group consisting of GpBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and GpBR322 (Pst)/HFIF7 (DSM 1793), under hybridizing conditions comprising using, at 68° C., a hybridizing solution that includes 0.75M NaCl and a washing solution that includes 0.3M NaCl, wherein such hybridization would produce a result above background.

In other words, the parties appear to agree that one may determine whether a DNA sequence is “capable of hybridizing” to one of the four DNA inserts recited in claim 1 by conducting a Southern blot experiment. Bayer contends that, although the parties’ construction is silent with respect to experimental conditions other than temperature and sodium chloride (NaCl) concentration, the term “comprising” means the test can include additional, unrecited conditions. *Id.* at 8. Bayer argues that its expert applied these two required conditions, and that it is irrelevant that its expert also used additional conditions. *Id.* at 27-28. In addition, while claim 1 is silent with respect to how to assess the results of the hybridization experiment, the parties stipulated that “such hybridization would produce a result above background” (or “signal above background”).

²³ Both Hif-2h and Clone 4 encode the same interferon- α polypeptide. *Id.* at 13. The Weissmann patent discloses Hif-2h but not Clone 4. It is undisputed that during this lawsuit, in 2010 or 2011, Bayer’s expert, Dr. Jeffrey Ravetch, and Bayer’s attorneys designed a version of interferon- α DNA that would have the “greatest likelihood of hybridizing” to the claim 1 DNA inserts; that DNA sequence is called “Clone 4.” Bayer’s Reply to Biogen’s Response to Bayer’s SOF (Motion No. 6), ECF No. 643-1 ¶ 68. Bayer contends that whether Clone 4 is in the prior art is irrelevant because Clone 4 is merely a way of showing that interferon- α falls within claim 1. *Id.* ¶¶ 69-70.

By contrast, Biogen contends that Bayer has failed to show that the Weissmann patent discloses each and every element of claim 1. Specifically, according to Biogen, claim 1 requires the existence of *both* the DNA sequence for interferon- α *and* Clone 4. While the Weissmann patent discloses a genus of trillions of DNA sequences that code for interferon- α , it discloses neither Clone 4, any specific DNA sequences that would hybridize to the disclosed interferon- α DNA sequences, nor any specific DNA sequences that are degenerate to the disclosed interferon- α DNA sequences. ECF No. 633 at 25-26. Biogen also argues, *inter alia*, that its own expert's experiments showed no hybridization between Clone 4 and HFIF3 or HFIF6, and that Bayer's hybridization evidence contravenes the parties' construction because Bayer's expert used experimental conditions that differed from those prescribed by claim 1. *Id.* at 27-31.

Bayer's motion presents another "battle of the experts" that is not suitable to resolution on summary judgment. *See Crown Packaging*, 635 F.3d at 1384; *B-K Lighting*, 375 F. App'x at 32; *Transonic Sys.*, 143 F. App'x at 330; *Total Containment*, 1999 WL 717946, at *4; *Leader Techs.*, 2011 WL 1514701, at *2. Each side criticizes the other side's hybridization experiments as being either poorly designed or improperly conducted. For instance, Bayer complains that Biogen's expert's experiment that purportedly showed no hybridization between Clone 4 and the claim 1 DNA inserts used 10,000 times less the amount of DNA than Bayer's expert had used. ECF No. 627-1 at 37-38. Biogen complains that Bayer's expert only used one concentration of sample DNA, ran the test only once, used a broken test gel, and used more sodium salt than the amount recited in claim 1. ECF No. 633 at 20-21. A jury will need to weigh the testimony of Bayer's experts against the testimony of Biogen's experts. Based on the present record, and construing all facts and inferences in a light most favorable to Biogen, a reasonable jury could find that Clone 4

and the claim 1 DNA inserts do not hybridize. Moreover, a reasonable jury could reject either or both Bayer's and Biogen's experts' experiments as poorly designed or improperly conducted.

Accordingly, the Court denies Bayer's motion for summary judgment of invalidity based on anticipation by the Weissmann patent.

V. CONCLUSION

For the reasons discussed above, the Court denies Serono's and Bayer's motions for summary judgment (ECF Nos. 501, 503, 505, 506, 509, 513, 517, 624). An appropriate Order accompanies this Opinion.

Date: January 9, 2018



HON. CLAIRE C. CECCHI
United States District Judge